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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,775	02/05/2004	Shuqi Chen	IQA-009.01	7895

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,775	CHEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/6/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-37,44,45,47-80 and 85-91* is/are pending in the application.

4a) Of the above claim(s) *11-13,19-21,33-35 and 48-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14-18,23-32,36,37,44,45,47,76-80 and 85-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 5, 14, 21, 23, 30-35, 47-52 is acknowledged and has been entered.

2. Applicant's addition of claims 85-91 is acknowledged and has been entered.

3. Applicant's cancellation of claims 38-43, 46, 81-84 is acknowledged and has been entered.

4. Claims 1-10, 14-18, 23-32, 36, 37, 44, 45, 47, 76-80, 85-91 are currently under examination.

5. Claims 11-13, 19-21, 33-35, 48-75 have been withdrawn.

Election/Restrictions

6. Applicant's election without traverse of a substance capable of specific binding to a preselected component of a sample in the reply filed on April 2, 2008 is acknowledged. As applicant has noted, this would encompass all the other species listed in the election of species requirement, rendering the species election moot.

7. Therefore, the election of species mailed March 4, 2008 has been withdrawn.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 5-10, 14-16, 23, 29-32, 36-37, 45, 76, 77, 85-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. [US 5,422,271].

With respect to claim 1, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65), the compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52). Furthermore, in the arrangement disclosed by Chen et al., the segments are arranged such that the distal ends of the segments are located at the distal ends of the other segments.

10. With respect to claim 2, Chen et al. teach a detection compartment for optical detection, which would require transparent portion (column 4, lines 31-45).

11. With respect to claims 5-10, Chen et al. teach nucleic acids hybridized to a detection site comprising an immobilized probe (column 2, lines 20-25), which may be nucleic acids (column 6, lines 1-25).

12. With respect to claims 14-16, Chen et al. teach probes immobilized to a detection site (column 2, lines 20-25), wherein the detection site may comprise beads anchored in place (column 3, lines 55-60), which would essentially form a coating.

13. With respect to claim 23, Chen et al. teach a closure cap (column 4, lines 48-50).

14. With respect to claims 29-31, Chen et al. teach a frame comprising rollers (column 4, lines 50-60) which would roll over the proximal ends of the segments (fig.1). Chen et al. further teach a closure cap to seal the passageway and to prevent carry over contamination (column 4, lines 40-50).

15. With respect to claim 32, Chen et al. teach storage compartments comprising amplification material (column 2, lines 35-41).

16. With respect to claims 36-37, the seals taught by Chen et al. (column 9, liens 17-25) are peelable, as they are formed by different layers pressed together.

17. With respect to claim 39, Chen et al. teach compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52).

18. With respect to claim 45, the segments form a substantially contiguous array (fig. 1).

19. With respect to claim 76, the reagents may be in dry format, such as with the probe spots (column 9, lines 40-42).

20. With respect to claim 77, the seals taught by Chen et al. (column 9, liens 17-25) are formed by different layers pressed together and would therefore leave no obstructions behind.

21. With respect to claims 85-90, Chen et al. teach compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), which would include nucleic acids and reverse transcription reagents and DNA polymerase (column 6, lines 34-46), primers (column 4, lines 8-10), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution

buffers (column 9, lines 50-52). Since the segments are all arranged such that the distal ends of the segments are connected to a main stream, all the segments would be located at the distal ends of the other segments.

22. With respect to claim 91, Chen et al. teach that the sample is nucleic acid material (column 2, lines 34-52), which would bind to nucleic acids.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 3, 24-28, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 5,422,271] in view of Chen et al. [US 2003/0049833].

With respect to claim 3, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65), the compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52). Chen et al. fail to teach the presence of pressure gates in fluid communication with the segments.

Chen et al., however, teach the use of pressure gates in fluid communication with tubules, in order to selectively control the flow of fluid between segments, lumens and other portions of the tubule, while also allowing the segments to be re-closeable (para. 0056).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used pressure gates in fluid communication with the segments, particularly as the breakable seals of Chen et al., as suggested by Chen et al., in order to selectively control the flow of fluid between segments, lumens and other portions of the tubule, while also allowing the segments to be re-closeable.

25. With respect to claims 24-28, Chen et al. teach the invention as discussed above. In particular, Chen et al. teach a closure cap (column 4, lines 48-50) for use with a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52), wherein the hole covered by the cap would also act as a vent. Chen et al. fail to teach that the cap comprises a sample collection device such as a swab.

Chen et al., however, teaches a cover that includes a sample collection instrument in the form of a tissue swab for collecting tissue samples from a sample source (column 2, lines 49-65) and further teach that this facilitates delivery of the sample to the tubule.

One of ordinary skill in the art at the time of the invention would therefore have found it obvious to utilize a cap comprising a sample collection device such as a swab in order to facilitate delivery of a sample to the tubule without any unnecessary contamination.

26. Claims 4, 17, 18, are rejected 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 5,422,271] in view of Presnell et al. [US 2003/0134390].

With respect to claims 4, 17, 18, Chen et al. teach the use of beads, but fail to teach the use of filters or silica beads.

Presnell et al., however, teach the use of silica beads, and further teach that these commercially available, and are methods for binding receptors to the beads are well known in the art (para. 0086). Presnell et al. further teach that the beads can be used for purifying samples, thus acting as a filter (para. 0142).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to use silica beads in the device of Chen et al., and further to use them as filters, as suggested by Presnell et al., in order to more easily produce the device of Chen et al. by using resources commonly available at the time, and also to obtain better data by purifying the sample.

27. Claims 44, 47, 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 5,422,271] in view of Miethe et al. [US 6,488,894].

With respect to claims 44, 47, 78-80, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65), the compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52).

Furthermore, in the arrangement disclosed by Chen et al., the segments are arranged such that the distal ends of the segments are located at the distal ends of the other segments. Chen et al., however, fail to teach that the segments for a substantially linear array.

Miethe et al., however, teach a device comprising a segregated reagent column (column 2, lines 38-55) comprising chambers in a linear, contiguous array (fig. 1-3) and further teaches that this allows for a precise, chronologically defined and sequential discharge of different reagents without prior mixing of the reagents in a simple manner (column 2, lines 31-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the segments of Chen et al. to be arranged in a substantially linear array, as suggested by Miethe et al., in order to allow for a precise, chronologically defined and sequential discharge of different reagents without prior mixing of the reagents in a simple manner.

Response to Arguments

28. Applicant's arguments with respect to claims 1-10, 14-18, 23-32, 36, 37, 44, 45, 47, 76-80, 85-91 have been considered but are moot in view of the new ground(s) of rejection.

29. Since some of the limitations, in particular that the array is linear was the completely addressed in the prior office action, the office action has not been made final.

Conclusion

30. No claims are allowed.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641